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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,463	10/14/2004	Yuval Simha Landschaft	RO0908US (#905668)	9282
7590 10/16/2008 D Peter Hochberg Company Baker Building 1940 East 6th St. 6th Floor Cleveland, OH 44114-2294				
EXAMINER MOHAMED, ABDEL A				
ART UNIT		PAPER NUMBER		
1654				
MAIL DATE		DELIVERY MODE		
10/16/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,463

Applicant(s)

LANDSCHAFT, YUVAL SIMHA

Examiner

ABDEL A. MOHAMED

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 10, 12, 13 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1, 8 and 10 is/are rejected.
- 7) ☒ Claim(s) 2-6, 12, 13, 16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

1. The amendment and remarks filed 06/16/08 are acknowledged, entered and considered. In view of Applicants request claims 1 and 18 have been amended, claim 9 has been canceled. Claims 1-6, 8, 10, 12, 13 and 16-18 are now pending in the application. The rejection under 35 U.S.C. 102(b) for claims 1-3 and 35 U.S.C. 103(a) for claims 2-6, 12, 13 and 16-18 are withdrawn in view of Applicant's amendment and remarks filed 06/16/08. However, the rejection under 35 U.S.C. 103(a) over Yamamoto et al (U.S. Patent No. 5,759,445) for claims 1, 8 and 10 is maintained for the reasons of record.

CLAIMS REJECTION-35 U.S.C. § 103(a)

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al (U.S. Patent No. 5,759,445).

It is noted that Applicant has amended by incorporating the limitation of claim 9 into independent claim 1 and thereby cancelling claim 9. Because of this amendment

and remarks the rejection under 35 U.S.C. 103(a) over the combined teachings of the prior art for claims 2-6, 12, 13 and 16-18 is withdrawn. However, the 103(a) rejection for claims 1, 8 and 10 is modified to 103(a) rejection over Yamamoto et al reference. This is not a new ground of rejection since Applicant has received the 102(a) rejection over the same reference previously. Further, the new ground of rejection is necessitated by Applicant's amendment to the claims. Thus, this does not preclude the Examiner from making this Office action Final.

The reference of Yamamoto et al ('445 patent) discloses an aqueous dispersed solution, which comprises the steps of evaporating an organic solvent from a mixture prepared by adding cholesterol, lecithin, a surfactant and a neutral lipid, and/or a cholesterol ester in the organic solvent in a specific range of the concentration ratio. The reference discloses the use of sodium cholate as the bile salt and tristearin (a sort of triglycerides), which is considered as a nutrient and sodium as ionic compound (See Examples 1-3). The preferred weight ratio of the sum of the cholesterol and cholesterol ester to the lecithin is from 1:1 to 1:2, a weight ratio of the neutral lipid to the lecithin is from 1:10 to 1:5, and a concentration of the lecithin is not more than 1,000 mg/dl when the lecithin is finally dispersed in a water or buffer, and as such overlaps with the claimed ratio of claim 1 (See e.g. Summary of the Invention and claim 4) as directed to claims 1, 8 and 10. With respect to the organic sulfur compound of claim 1, since the organic sulfur compound is optional it need not be present.

The Examiner acknowledges that the reference of Yamamoto et al is not intended for transdermal drug delivery, but the reference has the same composition as

claimed, which is a mixture is a mixture of lecithin, bile salt and cholesterol and used as a standard solution for determining lipid levels. Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969).

Therefore, the claimed specific amounts of lecithin, bile salt, cholesterol, and the ratio of by weight of lecithin, bile salts and cholesterol, which fall within the scope of the prior art would have been *prima facie* obvious from said prior art disclosure to a person of ordinary skill in the art at the time the invention was made because in the absence of sufficient objective factual evidence or unexpected results to the contrary, Applicant's claims are directed to optimization of an "art recognized variable" which is well within the purview of one of ordinary skill in the art, *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

OBJECTION TO CLAIMS, ALLOWABLE SUBJECT MATTER

3. Claims 2-6, 12, 13, 16 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

ACTION IS FINAL, NEC ESSITATED BY AMENDMENT

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

CONCLUSION AND FUTURE CORRESPONDANCE

5. Claims 1, 8 and 10 are rejected, claims 2-6, 12, 13, 16 and 17 are objected and claim 18 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABDEL A. MOHAMED whose telephone number is (571)272-0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mohamed/A. A. M./
Examiner, Art Unit 1654

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657